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ABSTRACT

This paper identifies typical sampling problems, including improper application of the Central Limit Theorem, that are associated with the probability-based sampling procedures currently used in clinical psychology research. It then presents two alternative research designs, the theory validation model and the extended case study model, which avoid some or all of these sampling problems. Both these models are based on purposive sampling, a type of non-probability sampling, which selects subjects according to a psychological theory and relates the results back to that theory. The procedural steps for each model are listed and the key advantages in assuring validity are outlined. These advantages are: (1) replication is built into each design through multiple experiments or cases; (2) data are interpreted in terms of a theory and generalized to a theory, rather than to a population; (3) data are gathered in naturalistic, clinical settings; and (4) small sample research is likely to have smaller or less bias using purposive sampling than using probability-based sampling. (JGL)

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PURPOSIVE SAMPLING IN CLINICAL RESEARCH

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Abstract

The purpose of this paper is to identify current problems in clinical research which can be associated with difficulties in sampling, and to offer the foundation for reasoned research strategies which are, in part, free from such sampling problems. Initially, sampling problems in clinical research will be identified. Subsequently, the particular "point of view" of this paper will be presented as one possible pragmatic solution to sampling dilemmas encountered in clinical research. And, this paper's point of view will be based on purposive or nonprobability models of sampling. Finally, two alternative research strategies based upon purposive sampling models will be provisionally suggested and illustrated.

Introduction and Background

The advent of cost indexing formulas implemented by the Department of Human Health Services for determining hospital reimbursement based upon a client's classification into diagnostic related groups (DRG's) versus actual cost of health care has created a great need and demand for empirical evidence of service delivery effectiveness and efficiency for all health related disciplines. Similarly, within the school system setting certain health and educationally related disciplines such as occupational therapy, psychology and physical therapy are under greater pressure to document worth and effectiveness of services in the educational setting. Thus, there is increasing pressure on almost all fields related to medicine and/or education to provide documentation of intervention strategies and treatment efficicacy (Gillette, 1982): Such documentation usually takes the form of a data base derived from the exectuion of clinical research.

Clinical research may be considered to be a specialized form of applied research having some unique characteristics which are specified as follows (Royeen, 1986). First, clinical research employs subjects identified as deviating from normal in some way, even if a comparison or control group is composed of normal subjects. Second, clinical research centers on research questions which, when answered, will influence the evaluation or treatment of individuals

characterized by a particular deviation from normal. Third and finally, clinical research is usually based upon relatively small samples since acquisition of subjects with identified and specified deviations from the norm is often difficult.

Due to the unique characteristics of clinical research, traditional research methodologies of experimental design (Kirk, 1968) and even quasi-experimental design (Campell & Stanley, 1966) is often problematic (Ottenbacher & Bonder, 1986). Consequently, in addition to refining and promoting such traditional research methodologies for use in clinical research, there is a need to promote alternative research methodologies in clinical research as a way to expand it's breadth and ease of implementation. The following are some of the ways suggested in the literature to accomplish this goal.

* Evaluation and reassessment of traditional parametric data analysis procedures used in clinical research (Lezak & Gray, 1985; Royeen & Seaver, 1986);

* Improvement of research designs for measurement of change (Fortune & Hutson, 1984);

* Increased use of qualitative research methodologies (Litterest, 1986; Schmidt, 1982);

* Reevaluation of the "significance" of tests of significance (Feinstein, 1977), and;

* Refinement of traditional sampling techniques (Fortune & Bender, in press).

Yet another strategy may mitigate some of the sampling problems inherent in clinical research and offer another

avenue for clinical investigations: Alternative research methodologies adapted from other disciplines can modified and employed in clinical research. These will be addressed subsequent to a discussion of sampling dilemmas in clinical research.

Analysis of Sampling Problems in Clinical Research

Sampling dilemmas in clinical research were identified in the following way. First, research literature within a clinical practice profession, occupational therapy, was indexed from 1980 to 1986 for use in a separate investigation (FN1). Second, sampling problems identified in the literature were reviewed (Feinstein, 1977; Lezak & Gray 1985; Porgis, 1979; Tupper & Rosenblood, 1984). Third, experience on part of the authors as consultants to and executors of clinical research was considered. In summary, the most common sampling dilemmas in clinical research are presented as follows in Figure 1.

[Insert Figure 1 here.]

Review of Figure 1 reveal numerous sampling dilemmas in clinical research. Not all, but at least some portion, of these delimmas are intimately related to or exacerbated by the requirements of probability sampling. It may be that for some research investigations, movement away from probability sampling to nonprobability sampling will

mitigate confounding sampling effects identified in Figure 1.

Purposive versus Probability Models of Sampling

One may ask why applied researchers depend so heavily on the use of probability models in the design of clinical research given the sampling dilemmas in encountered therein. This reliance may be due to the contribution of the probability model in control of study design. For, application of the Central Limit Theorem in probability sampling permits the investigator to control error in the generation of unbiased parameter estimates and to create normally distributed test statistics required in many statistical analyses.

The Central Limit Theorem states:

> "As the sample size "n" becomes large, the sampling distribution of the sample mean can be approximated by a normal distribution with a mean of mu and a standard deviation of sigma devided by the squareroot of "n", where mu is the mean of the population and the sigma is the standard deviation." (p. 241, Mansfield, 1986)

This theorem can be applied directly to estimate, in an unbiased manner, key parameters in survey sampling. Or, the theory can be applied to establish a test statistic through its application to the distribution of a selected parameter of the sample, such as the mean, in repeated samples from the same population. In the second application of the theorem, it is the sample parameter, not the variable being sampled, that is normally distributed. Herein lies the potential for

"false security" often inappropriately attributed to the Central Limit Theorem: Many researchers justify the assumption of the normal distribution of a variable using the Central Limit Theorem when, in fact, the Central limit Theorem refers only to the parameter of the sampling statistic. Moreover, the finite population from which samples derive in clinical research has adverse implications for the appropriateness of the Central Limit Theorem in clinical research (Plane & Gorden, 1982).

Given (a) existing sampling problems in clinical research which can associated, in part, with probability sampling, and (b) the questionable use of the Central Limit Theorem in justifying sampling techniques (since it may not subserve samples from finate popuations), a sampling process and the foundation for concomitant research designs based upon nonprobability sampling will be presented as alternatives. Within these designs, the use of purposive sampling obliges the clinical inverstigator to discern a plan through which sampling controls (unbiased estimates, accuracy of estimates, representativeness and practicality of results) can be approximated. Theoretical foundation or theory reference in purposive sampling may be the link to allow for such control in purposive sampling.

Theoretical Foundations of This Paper's Point of View

The foundation for alternative research strategies to be subsequently presented in this paper is based upon purposive

sampling which is a non-probability sampling procedure. Sills (1968) defines nonprobability sampling as:

> ... the selection of sampling units for a statistical study according to some criterion other than a probability mechanism (p. 612, Sills, 1968).

Purposive sampling is a specilized form of nonprobability sampling. Purposive sampling refers to the choice of a sample or sampling unit based upon certain characteristics or manifestations (Hansen, Hurwitz & Madow, 1953). As previously stated, the criterion proposed herein for guidance of the sample selection is theory. For, just as Chen and Rossi (1983, 1987) propose an alternative way of considering implementation of evaluation research and validity which is "theory driven", so too we argue for theory driven purposive sampling as one possible way to implement alternative research strategies in clinical research. If the purpose of science is to develop theory (Mason & Bramble, 1978), and if theory should be well grounded or evolve from the data (Glasser & Strauss, 1967), then it would seem logical to develop and/or refine research strategies for clinical research that employ theory as a guide for subject/sample selection as seen in purposive sampling.

In consideration of this, the foundation for two research strategies or plans are now presented which are predicated upon purposive sampling. These are presented as additional research plans to employ in clinical research and are not presented as hierarchically higher or lower (Yin, 1985) than other research strategies. Rather, they are presented as merely additionally ways to develop and document

a rich and varied data base in clinical research.

Strategies for Clinical Research Based upon Purposive Sampling

Theory Validation Model

Review of literature in experimental psychology reveals a common practice exemplified by Barber and Winefield (1986) and Lederman and Taylor (1972). In each case, a theoretical reference (learned helplessness theory and a theory of active touch, respectively) was tested by conducting consecutive laboratory experiments designed to explore an aspect of the identified theory by administering some test or experimental conditions. Note that subject samples were derived from university students. The field of experimental psychology is considered to conduct scientifically sound research. What appears to allow for the validity of the experiments and the ensuing interpretations is that they are designed to test and explore theory and results are discussed in terms of theory, rather than as generalizations to populations. Moreover, replication of experiments in varying formats allows for "truth" or validity of interpretations to emerge. Inherent within this design is manipulation of some condition or variable (and variations thereof) within the series of experiments.

It seems that this model can be adapted and applied as

a foundation for research design in the conduct of clinical research. However, the major design difference between how the design is employed in experimental psychology compared to how it might be employed in clinical research would be sampling. Experimental psychology primarly uses samples of convenience, hence the preponderence of undergraduate psychology students. Somewhat differently, samples or subjects for clinical investigation would be chosen according to criteria generated from the theory to be investigated. Simply, the components of the research design may be as follow.

Steps in Theory Validation Model.

(1) Define or describe theoretical reference or the model subserving the investigation.
(2) Identify research questions pertaining to the model and generate hypotheses or propositions based upon the theoretical reference.
(3) Describe the hallmark conditions or clinical symptomology that theoretical considerations would require for subject/sample characteristics. Define how to identify that symptomology and provide explanations of how it relates to the identified theory. Identify and select subjects/samples based upon such purposive sampling using conditions or characteristics of sample as selection critia.
(4) Conceptualize a minimum of three sequential experiments designed to demonstrate or address the hypotheses or

propositions (or variations thereof) in a variety of ways and conditons. Identify how each individual experiment addresses the theory and how the experiments considered as a whole address the theory. [A key in this theory validation model is the delivery of some or all of a clinically based intervention as the experiment.]

(5) Execute the series of experiments. The same subject or different subjects may serve in each experiment, depending upon how the experiments are designed.

(6) Identify how data derived for each subject/sample addresses or relates to the posited hypotheses or propositions.

(6) Relate results and generalize interpretations to theory from which the original hypotheses or propositions were derived.

Extended Case Study Model

This research plan is based upon what is commonly known as "case study" or multiple case study investigation (Isaac and Michaels, 1984; Yin, 1984;1985). Case study research can be used for multiple reasons such as explanation, description and testing of theory (Yin, 1985). Much of the foundation of psychiatry and psychology is based upon what may be considered primitive forms of case study methods as evidenced in the work of Freud (1924) and Piaget (1954). The rigorous research methodology of case study investigations is today

common in educational research and research conducted for governmental agecies.

Note that this model does not have an intervention component as strongly embedded as did the theory valdiation model. For example, the theory validation model allows for variation in clincial intervention as a way to assess effects related to theory. In the extended case study model, delivery of clinical intervention and the effects related to theory is of less concern contrasted to the identification and manifestion of subject behaviors, attitudes, etc. as part of the description or domain specification related to a clinical phenomenon.

Steps in Extended Case Study Model

(1) Identify the theory or model of interest which will serve to "drive" or be the foundation of the research.
(2) Pose hypotheses or propositions predicting behaviors or findings based upon the theoretical model.
(3) Select or purposively sample at least three cases based upon what the theory would predict, i.e., extreme cases, typical cases, exceptional cases.
(4) Execute detailed and in-depth analyses of the case to determine if, indeed, the case explempifies what theory would predict.
(5) Explain the results of each case individually related to the initial hypotheses or formulations.
(6) Relate the results of the cases overall to the original

theory generating the investigation. Identify changes or modifications to theory which may be appropriate.

Conclusion

The foundation for clinically based research strategies proposed herein may be considered as form of field based research even if quantitative and qualitative procedures are part of the research protocal embedded within the research plan. Issues osf external validty are ameliorated in these two designs based upon purposive sampling since:

(1) Replication is a key built into each design through multiple (minimum of three) experiements or cases;

(2) The critical issue is interpretation and generalization of theory versus interpretation and generalization to some population;

(3) Data is gathers in naturalistic, clinical settings - enhancing the relvance and functional application of the interpretations (Stainback & Stainback, 1984);

(4) Small sample research is likely to have smaller or less bias using purposive samplign than small sample research using probability samples (Hanse, Horwitz, & Madow, (1953).

In closing, these research plans are presented as foundations to be elaborated and embellished using rigorous standards of defitions, procedures and interpretation criteria.

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No.	Sampling Dilemma Explanation of Effect
1	Low Frequency of Occurence Many phenomenon of interest to clinical investigators are rarely occuring dysfunctions. Therefore, it is difficult to generate sufficient sample sizes when random sampling is employed.
2.	Small Group Nesting of Subjects The nesting of subjects into small groups within a large number of clinics or settings creates the potential of two design problems. First, the smaller the subgroups, the larger the sample size that is required to measure the effects of the nesting and the less likely a study based on the entire clientele of one or a few clinics may be appropriate. Second, selection factors for the nesting are apt to be stronger and more difficult to control through the design. These factors, caused by demographic differences, self-selection on part of clients, and differences with regard to theoretical assumptions concerning treatment application, expand the error term in any comparative investigation.
3.	Diagnostic Nature of Subject Definition Subjects come to clinics for the remediation of a problem resulting from a collection of symptoms. They are then diagnosed into a treatment classification through a variety of accepted methods. The accuracy of this process is always limited. Accuracy can fail in one of two ways; the subjects may be misclassified or the treatment classification may contain more than one syndrome or dysfunction.
4.	Unknown Population Parameters Often, the clinical phenonmenon of interest is so new or so little is know about it that the population from which it may be considered a subsample has not only unknown parameters, but it is a truly unknown population.

5. Prior Effects from History May be Present

The clients come to clinics with, hypothetically, large variances in prior treatment of the dysfunction, life styles, and intensity of dysfunction. The prior treatments may interact with current treatment (the independent variable) or research design requirements.

6. Lability of Marker Variables for Subject Identification

A hallmark of many dysfunctions is lability. Thus, to try and identify a sample based upon static measurements in time which are not necessarity related to theory may not reflect the true status of the dynamic character of variable(s) of interest.

7. Multiple Threats to Uniform Conditions

Differences in dispositions of theory concerning practice, available resources and equipment, administrative requirements of individual clinics, and training and skill of therapists make uniformity of treatment and measurement unlikely across large numbers of different clinics or settings.

8. Comparison of Dysfunction to Normality

An often used sampling strategy is to compare individuals with known deviations from normal to "normals" when, by definition, the group or subjects with deviations from normal systematically differ from the norm on important characteristics. Thus, using "normals" as a control or contrast group may be questionable in terms of logic and validity.

9. Necessity of Disclosure

In clinical investigations the client must give consent to participate. The number of clients unwilling to participate predicates that those who undergo study are more like volunteer subjects than randomly selected subjects. Efforts to gain consent frequently require detailed explanation of the study. Such explanation may result in the Hawthorn effect. Due to ethics of practice all clients should receive some form of legitimate treatment. Hence, true controls (the absence of treatment) may not be a study alternative.

Figure 1. Sampling Dilemmas in Clinical Research

Footnote

FN1. The following journals were indexed:

American Journal of Occupational Therapy

Occupational Therapy in Mental Health

Occupational Therapy Journal of Research

Physical and Occupational Therapy in Geriatrics

Physical and Occupational Therapy in Pediatrics